K000673 Page 1 of 2

MAY 2 6 2000

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RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date Prepared: February 25, 2000
Company / Institution name: RICHARD WOLF MEDICAL INSTRUMENTS CORP.			**FDA establishment registration number:** 14 184 79
Division name (if applicable): N.A.			**Phone number (include area code):** (847) 913-1113
Street address: 353 Corporate Woods Parkway			**FAX number (include area code):** (847) 913-0924
City: Vernon Hills	**State/Province:** Illinois	**Country:** USA	**ZIP / Postal Code:** 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information	
Trade name: Hysteroscope Sheath and Insert	**Model number:** 8988.031, 8988.041, 8988.231, 8988.241
Common name: Hysteroscope Sheath and Insert	**Classification name:** Hysteroscope and Accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-enact.	1 Hysteroscopes and Accessories 4995, 4997, 4999, 8999	1 Richard Wolf
2 K880314/B	2 Hysteroscope Autonom 4995	2 Richard Wolf
3 K895857/A	3 Resectoscope and Accessories	3 Richard Wolf
4	4	4

1.0 Description

The submitted operating sheaths and inserts are used with endoscopes in hysteroscopy.

2.0 Intended Use

Operating Hysteroscopes are used to visualize and to operate in the cervical channel and the cavum uteri via natural accesses.

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3.0 Technological Characteristics

The submitted inserts can be combined with all sheaths. They are connected with snap-on and bayonet locking.

The added working channel enables the sheaths to be used for diagnosis and for operating with instruments.

A dual channel system provides continuous irrigation / distension.

A fixed and a controllable ramp facilitates operating on lateral objects.

Snap-on locking facilitates connecting the sheath to the insert.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing pre-enactment and 510(k) devices sold by Richard Wolf.

5.0 Performance Data

No performance standards are known.

6.0 Clinical Tests

Clinical tests were not performed.

7.0 Conclusions

These devices are designed and tested to assure their safety and effectiveness when used according to the instructions manual.

By: Robert L. Casarsa Date: Feb 24, 2000

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 2000

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, IL 60061

Re: K000673
Hysteroscope Operating Sheaths and Inserts
Dated: February 25, 2000
Received: February 28, 2000
Regulatory Class: II
21 CFR §884.1690/Procode: 85 HIH

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

[redacted]

510(k) Number (if known): K000673

Device Name: Hysteroscope Operating Sheaths and Inserts

Intended Use:

Operating Hysteroscopes are used to visualize and to operate on the cervical channel and the cavum uteri via natural accesses.

Indications and Application:

The Operating Hysteroscopes are used for the examination and diagnosis in connection with endoscopic accessories in the discipline of gynecology. The Operating Hysteroscopes are indicated for the following examinations:

- Abnormal bleeding
- Fertility
- Lower abdomen complaints
- Myomas, polyps, ablation of endometrium

The examination must be performed be adequately trained and qualified medical personnel.

Contraindications:

- Acute inflammation of the lower abdomen
- Vaginal infection
- Cervical channel infection
- Pregnancy

Contraindications directed related to the product are presently unknown. The attending physician must decide if the intervention is appropriate.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000673

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter

Combinations:

△ *CAUTION!*

When various products are used in conjunction, it is necessary that the intended use and relevant technical data, i.e, working length, diameter, etc., correspond. Comply with the product instruction manuals used in combination with this product.

Operating Hysteroscopes are used in connection with light sources and flexible light cables or photo reflex cameras, hystero pumps, or hystero CO_2 Pneu automatic insufflators.

Endoscope accessories comprise the following components:

- 400μ Laser fiber without CO_2 cooling
- 3 Fr. Auxiliary instruments, minimum working length 350 mm (uninsulated biopsy forceps, uninsulated foreign body grasping forceps)
- Handle for ergonomic work

△ *CAUTION!*

Danger of eye injuries if lasers are used!

If lasers are used, ensure the use of a suitable filter attachment on the eyepiece, as well as protection gear for the user(s).

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